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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

LU, FRANK WEI MIN

ART UNIT PAPER NUMBER

1634

DATE MAILED: 08/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/997,741

Applicant(s)

PHAN ET AL.

Examiner

Frank W Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,8,12 and 29-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 7, 9-11, 13-18, and 21-23 is/are rejected.
- 7) ☒ Claim(s) 2-4, 19, 20 and 24-28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/9/2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4/2005. 6) ☐ Other:

DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission of RCE filed on April 13, 2005 have been entered. The claims pending in this application are claims 1-28. In view of recent search results, the examiner decides to withdraw the allowance mailed on January 13, 2005 and sends a non-final action. Since claims 5, 6, 8, 12, and 29-60 have been withdrawn due to restriction requirement and species election, claims 1-4, 7, 9-11, and 13-28 will be examined.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1, 7, 10, 11, 13, 17, 18, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nilsen *et al.*, (US Patent No. 5,484,904, published on January 16, 1996) in view of Van Ness *et al.*, (US Patent No. 5,106,730, published on April 21, 1992).

Regarding claim 1, Nilsen *et al.*, teach mixing capture beads (ie., beads A), each having at least one transport probe affixed thereto, reporter beads (ie., beads B), each having at least one signal probe affixed thereto, and a biological sample (ie., the sequence to be detected), under binding conditions so as to permit formation of a dual bead complex if the target agent is present in the sample, the reporter bead and capture bead each being bound to the target agent (see Figure 5, column 4, lines 36-38 and column 18); isolating the dual bead complex from the mixture to obtain an isolate (see column 18); exposing the isolate to a capture field on a support, the capture field having a capture agent that binds to the dual bead complex (see Examples 1 and 2 in columns 18-20 and Figure 6); and detecting the presence of the dual bead complex to indicate that the target agent is present in the sample (ie., detecting the dual bead complex using labeled macrobeads, see columns 19 and 20).

Regarding claim 7, Nilsen *et al.*, teach that the detecting the presence of the dual bead complex includes directing light to the capture field and detecting light reflected from the capture field (ie., detecting fluorescent-labeled macrobeads in the aid of fluorescent microscopy, see columns 13 and 20).

Regarding claims 10, 11, 17, and 18, Nilsen *et al.*, teach that the target agent includes a nucleic acid and the transport probe and the signal probe include a nucleic acid molecule

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complementary to the target nucleic acid as recited in claims 10 and 11, the transport probes comprise one or more probes selected from the group consisting of: single-stranded DNA, double-stranded DNA, single-stranded RNA, peptide nucleic acid, biotin, streptavidin, an antigen, an antibody, a receptor protein and a ligand and the dual bead complex specifically binds to the capture agent via the signal probe or the reporter bead or any combination thereof as recited in claims 17 and 18 (see Figures 5 and 6).

Regarding claims 13, 22, and 23, Nilsen *et al.*, teach that the biological sample is selected from the group consisting of blood, serum, plasma, cerebrospinal fluid, breast aspirate, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, urine, saliva, amniotic fluid, semen, mucus, a hair, feces, a biological particulate suspension, a single-stranded or double-stranded nucleic acid molecule, a cell, an organ, a tissue, and a tissue extract as recited in claim 13 and the target agent is selected from the group consisting of a nucleic acid characteristic of a disease, a nucleic acid having a nucleotide sequence specific for a person, a nucleic acid having a nucleotide sequence specific for an organism, a nucleic acid molecule associated with cancer in a human, an antibody which is present only in a subject infected with HIV-1, a viral protein antigen, and a protein characteristic of a disease state in a subject as recited in claim 22, and the target agent includes a nucleic acid having a nucleotide sequence specific for an organism, and the organism is a bacterium, a virus, a mycoplasma, a fungus, a plant, or an animal as recited in claim 23 (see column 16, lines 48-67).

Nilsen *et al.*, do not disclose that a capture field is on a disc as recited in claim 1.

Van Ness *et al.*, teach that a capture oligonucleotide (ie., a capture field) is on a disc (ie., nytran discs) (see column 19).

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Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have performed the method recited in claim 1 in view of the patents of Nilsen *et al.*, and Van Ness *et al.*. One having ordinary skill in the art would have been motivated to do so because the simple substitution of one kind of support (ie., the support taught by Nilsen *et al.*,) from another kind of support (ie., the disc taught by Van Ness *et al.*,) during the process of making a support having a capture field, in the absence of convincing evidence to the contrary, would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06, 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements in such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

4. Claims 9, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nilsen *et al.*, in view of Van Ness *et al.*, as applied to claims 1, 7, 10, 11, 13, 17, 18, 22, and 23 above, further in view of Mirkin *et al.*, (US Patent No. 6,506,564 B1, filed on June 26, 2000).

The teachings of Nilsen *et al.*, and Van Ness *et al.*, have been summarized previously, *supra*.

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Regarding claim 16, since Nilsen *et al.*, teach to isolated the dual bead complex after mixing capture beads, reporter beads, and a biological sample (see above), Nilsen *et al.*, disclose that the mixing is intermittent and not continuous as recited in claim 16.

Nilsen *et al.*, and Van Ness *et al.*, do not teach that the reporter beads are fluorescent. However, Nilsen *et al.*, teach that the detecting the presence of the dual bead complex further comprises directing light at a wavelength, and detecting an emitted light at a wavelength as recited in claim 9 and teach that B bead can be labeled (see column 17, last paragraph and Figure 5).

Mirkin *et al.*, teach that one of beads in a hybridization assay is fluorescent labeled and is used for detecting the hybridization (see column 6, last paragraph bridging to column 7, first paragraph and Figure 3).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have performed the method recited in claims 9 and 15 wherein the reporter beads are fluorescent in view of the patents of Nilsen *et al.*, Van Ness *et al.*, and Mirkin *et al.*. One having ordinary skill in the art would have been motivated to do so because the simple substitution of one kind of fluorescent detection method (ie., the method taught by Nilsen *et al.*,) from another kind of fluorescent detection method (ie., the method taught by Mirkin *et al.*,) during the process of performing the method recited in claims 9 and 15, in the absence of convincing evidence to the contrary, would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made since the method taught by Nilsen *et al.*, and the method taught by Mirkin *et al.*, have an identical function (ie., detecting the hybridization).

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06, 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements in such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

5. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nilsen *et al.*, in view of Van Ness *et al.*, as applied to claims 1, 7, 10, 11, 13, 17, 18, 22, and 23 above, further in view of Mirkin *et al.*.

The teachings of Nilsen *et al.*, and Van Ness *et al.*, have been summarized previously, *supra*.

Nilsen *et al.*, and Van Ness *et al.*, do not teach that the reporter beads comprise latex, gold, plastic, steel, or titanium.

Mirkin *et al.*, teach that beads can be made by different material such as latex or gold (see columns 34-36).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have performed the method recited in claims 9 and 15 wherein the reporter beads are latex or gold in view of the patents of Nilsen *et al.*, Van Ness *et al.*, and Mirkin *et al.*. One having ordinary skill in the art would have been motivated to do so because the simple substitution of one kind of bead (ie., the bead taught by Nilsen *et al.*) from

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another kind of bead (ie., the beads taught by Mirkin *et al.*) during the process to making a reporter beads, in the absence of convincing evidence to the contrary, would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made since these beads used for making reporter beads are exchangeable.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06, 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements in such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

6. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nilsen *et al.*, in view of Van Ness *et al.*, as applied to claims 1, 7, 10, 11, 13, 17, 18, 22, and 23 above, further in view of Hornes *et al.* (US Patent No. 5,512,439, published on April 30, 1996).

The teachings of Nilsen *et al.*, and Van Ness *et al.*, have been summarized previously, *supra*.

Nilsen *et al.*, and Van Ness *et al.*, do not teach that the capture agent is affixed to the capture layer via an amino group or a thiol group as recited in claim 21.

Hornes *et al.*, teach that different function groups such as an amino group can be used to attach an oligonucleotide to a bead (see column 3, lines 41-52).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have performed the method recited in claim 21 wherein the capture agent is affixed to the capture layer via an amino group in view of the patents of Nilsen *et al.*, Van Ness *et al.*, and Hornes *et al.*. One having ordinary skill in the art would have been motivated to do so because the simple substitution of one kind of method (ie., the method taught by Nilsen *et al.*,) from another kind of method (ie., the method taught by Hornes *et al.*,) during the process to making a capture field by attaching an oligonucleotide to a capture layer, in the absence of convincing evidence to the contrary, would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made since the method taught by Nilsen *et al.*, and the method taught by Hornes *et al.*, have an identical function (ie., making a capture field by attaching an oligonucleotide to a capture layer).

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06, 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements in such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application

No.10/087,549. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims in this instant application is either anticipated by, or would have been obvious over, the reference claims. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Although claim 1 in this instant application are not identical to claim 1 of copending Application No.10/087,549, claim 1 in copending Application No.10/087,549 are directed to the same subject matter and fall entirely within the scope of claim 1 in this instant application. In other words, claim 1 in this instant application is anticipated by claim 1 of copending Application No.10/087,549.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion


9. No claim is allowed.
10. Claims 2-4, 19, 20, and 24-28 are objected to as being dependent upon a rejected base claim, but appear to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (571)272-0745.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
PSA
August 5, 2005


FRANK LU
PATENT EXAMINER